K123540
Page 1 of 3

SIEMENS

510(K) SUMMARY
FOR
SYNGO.CT PULMO 3D

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: August 16, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

AUG 2 9 2013

2. **Device Name and Classification**

Product Name:	syngo.CT Pulmo 3D
Propriety Trade Name:	syngo.CT Pulmo 3D
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

3. **Substantial Equivalence:**

Siemens syngo.CT Pulmo 3D post processing software package is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device Name	***FDA Clearance Number***	***FDA Clearance Date***
Siemens syngo® InSpace 4D	K071513	06/26/2007
Vida Pulmonary Workstation 2 (PW 2)	K083227	11/18/2008

SIEMENS

4. **Device Description:**
   syngo.CT Pulmo 3D allows the evaluation of lung tissue and airways. In contrast to lung function tests, CT evaluations can show the effect of a disease on the parenchyma and the airways. The lungs as well as the airways are segmented in the preprocessing, and divisions of the lungs like thirds, core/peel, and lung lobes are calculated.

5. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**
   syngo.CT Pulmo 3D software package has similar intended use as the predicate syngo® Inspace4D (K071513, clearance date 06/26/2007). syngo.CT Pulmo 3D is designed to be operated on syngo.via platform in a single or multi user environment.

   Airway segmentation and lung lobe calculation tools are provided with this software version.

6. **Nonclinical Testing:**
   syngo.CT Pulmo 3D is designed to fulfill the requirements of following standards:
   - IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
   - IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
   - ISO 14971:2007; Medical devices - Application of risk management to medical devices
   - DICOM (Digital Imaging and Communications in Medicine) Standard: 2008

   DICOM conformity is fully covered by syngo.via implementations.

   Non clinical tests were conducted for syngo.CT Pulmo 3D software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

   Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

7. **Indications for Use:**
   syngo.CT Pulmo 3D is an image analysis software for CT volume data sets. It analyses the lung, either completely or in parts, identifying areas with lower or higher Hounsfield values in comparison to a predefined threshold. These areas are evaluated using statistical methods such as histograms and percentiles.

SIEMENS

Using syngo.CT Pulmo 3D, you can examine the lung parenchyma and the airways of the lung.

The following evaluation tools are provided:

- Computation of lung volumes
- Display of statistics related to the lung
- Setting of markers
- Airway measurements

syngo.CT Pulmo 3D facilitates the reporting by using of appropriate reporting tools, for example, key image creation.

You can use syngo.CT Pulmo 3D to create a DICOM Structured Report.

8. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

9. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the syngo.CT Pulmo 3D software package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Siemens Medical Solution USA, Inc.
% Ms. Kimberly Mangum
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway, D02
MALVERN PA 19355-1406

Re: K123540
Trade/Device Name: syngo.CT Pulmo 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 16, 2013
Received: August 19, 2012

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123540

Device Name: **syngo.CT Pulmo 3D**

Indications for Use:

syngo.CT Pulmo 3D is an image analysis software for CT volume data sets. It analyses the lung, either completely or in parts, identifying areas with lower or higher Hounsfield values in comparison to a predefined threshold. These areas are evaluated using statistical methods such as histograms and percentiles.

Using syngo.CT Pulmo 3D, you can examine the lung parenchyma and the airways of the lung.

The following evaluation tools are provided:

- Computation of lung volumes
- Display of statistics related to the lung
- Setting of markers
- Airway measurements

syngo.CT Pulmo 3D facilitates the reporting by using of appropriate reporting tools, for example, key image creation.

You can use syngo.CT Pulmo 3D to create a DICOM Structured Report.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K123540___